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EXAMINER SZMAL, BRIAN SCOTT				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Chgpatent@leydig.com

Office Action Summary

Application No.

10/790,618

Applicant(s)

VAN DER STEEN ET AL.

Examiner

Brian Szmaj

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration.
See 37 CFR 1.52(c).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second activating means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

35 USC § 112, 6th Paragraph

3. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

4. Claim element "correlation detection means" in Claim 14 is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification fails to explicitly disclose if the claimed "correlation detection means" constitutes a software or hardware application.

Applicant is required to:

- (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or
- (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

5. Claim element “first activating means” in Claim 18, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification fails to explicitly disclose if the “first activating means” constitutes a software application or a hardware application.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

6. Claim element “second activating means” in Claim 19, is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to

the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function. The current specification fails to explicitly disclose if the "first activating means" constitutes a software application or a hardware application.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function.

For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 discloses a "correlation detection means". The current specification however fails to disclose the structure of the "correlation detection means".

9. Claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In Claim 18, the claimed "first activating means" is not clearly disclosed in the current specification with respect to the "first activating means" being either a software application or a hardware application. In Claim 19, the claimed "second activating means" is not clearly disclosed in the current specification with respect to the "first activating means" being either a software application or a hardware application.

10. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 25 and 26 disclose "wherein an optimum overlap is determined by means of a probability function representing similarity between consecutive signals". The current specification fails to disclose what probability function is being utilized to determine the optimum overlap. The current specification appears to imply every known probability function can be used to perform the task of determining the optimum overlap. The current specification also fails to disclose what signals are being used to determine

the optimum overlap, and how the optimum overlap is being used to determine hardness information of tissue.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 14, 18, 19, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 discloses a "correlation detection means". It is unclear to the Examiner if the claimed "correlation detection means" constitutes a software or hardware application.

Claims 18 and 19 disclose the "first activating means" and "second activating means". It is unclear to the Examiner if the claimed "first activating means" and "second activating means" constitute a software or hardware application. Furthermore, Claim 19 claims a second activating means, whereas Claim 13 fails to disclose a first activating means.

Claims 25 and 26 disclose the determination of an optimum overlap. In the context of the claims, in combination with their respective independent claims, it is unclear to the Examiner what the optimum overlap has to do with the method steps of generating tissue hardness information, and the apparatus elements for generating tissue hardness information. Based on the current claim language, it is also unclear how the optimum overlap is being used to generate tissue hardness information.

13. Claims 1-8, 10-12 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: processing the received signals to determine an optimum overlap in order to determine the measured strain of the tissue, such that the relation of the strain to either of hardness or elasticity of the tissue can be performed.
14. Claims 13-24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: how the use of an optimum overlap determined by the processor is used to determine the strain of the tissue, such that the hardness or elasticity of the tissue can be determined.

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 fails to provide a concrete result. The final step of relating the strain is not viewable by a user, such that the ultimate result obtained by the method is not capable of being reproduced because a user would not be able to verify the results.

17. Claims 14, 18, 19 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 14 discloses a "correlation detection means", but the current specification fails to disclose the structure constituting the "correlation detection means". Since the "correlation detection means" can be interpreted as a software application, the claimed "correlation detection means" lacks any sufficient structure and therefore is nonstatutory. Claims 18 and 19 disclose a "first activating means" and "second activating means", but the current specification fails to explicitly disclose the structure performing the activation, and therefore can be interpreted as a software application. Since the "first activating means" and "second activating means" can be interpreted as a software application, the claimed "first activating means" and "second activating means" lack any sufficient structure and therefore is nonstatutory. Claim 18 is also non-statutory because the current specification has not clearly defined the "memory means". The "memory means" can be interpreted as being either transitory, a signal, or non-transitory, a physical medium. Since the claimed "memory means" can be interpreted as being a signal, then the claim is non-statutory. In order to be statutory, the memory means must be limited to only a non-transitory medium. The claim language of Claim 22 constitutes the mixing of two statutory classes, method and apparatus. Since the claim is directed towards an apparatus, the claim language of "recording signals" constitutes a method step in the apparatus claim, and therefore constitutes non-statutory subject matter.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1) in view of Panescu et al (5,848,969).

Torp et al disclose a means for real-time calculation and display of strain in ultrasound imaging and further disclose receiving signals from a tissue with a sensor for measuring the deformation of the tissue in a measuring plane defined by the sensor (the measuring plane is defined by the sensor surface that is parallel to the tissue surface); the sensor is placed in a direction transverse to the measuring plane while being subject to a varying pressure (the catheter has ultrasound sensors oriented transversely to the longitudinal axis of the catheter, thus any movement in a vessel would have a movement being transverse to the measuring plane); a varying pressure exerted on the tissue; identifying strain of the tissue from the signals received by the sensor; relating the strain to at least one of either hardness or elasticity; correlating signals acquired consecutively over time, where the signals are representative of the deformation of the tissue at positions of the sensor moved with respect to other positions of the sensor; calculating by means of the correlating step, strain in a tissue surface or tissue volume part; displaying elasticity or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; displaying

elasticity or hardness parameters of the tissue with position information of the sensor or tissue; and signals possessing an overlap are received. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; Column 8, lines 8-17 and 53-67; and Column 9, lines 1-9.

Torp et al however fail to disclose the sensor is placed in a direction transverse to the measuring plane while being subject to a varying pressure; a varying pressure exerted on the tissue; the signals are received during practically continuous motion of the sensor; and the signals come from a blood vessel wall and the data is received only during a specific time period.

Porat et al disclose a means for tissue characterization and further disclose the sensor is placed in a direction transverse to the measuring plane while being subject to a varying pressure; a varying pressure exerted on the tissue; the signals are received during practically continuous motion of the sensor; and the signals come from a blood vessel wall and the data is received only during a specific time period. See Paragraphs 0286 and 0298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability to move the sensor within a blood vessel, as per the teachings of Porat et al, since it would provide a means of determining a tissue parameter along a length of tissue.

Torp et al and Porat et al however fail to explicitly disclose the use of an actuator to move the sensor; the signals are optical data detected with an optical sensor; the signals at as assumed cyclic pressure change are received at predetermined time

intervals in a pressure change cycle; and the tissue is an artery moving during a heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery.

Panescu et al disclose a means for visualizing internal structures and further disclose the signals are optical data detected with an optical sensor; the signals at assumed cyclic pressure change are received at predetermined time intervals in a pressure change cycle; the tissue is an artery moving during a heartbeat in the longitudinal direction (the bolus of blood coming from the heart expands the blood vessel outward and along the length of the blood vessel, in the same manner as the esophagus moving a bolus of food to the stomach), and the sensor is moved parallel to the longitudinal direction so that during at least one detection period the sensor has a fixed position relative to the wall of the artery. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to control the movement of the sensors, as per the teachings of Panescu et al, since it would provide a means of accurately measuring a tissue parameter along a length of tissue.

20. Claims 13, 14, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) in view of Porat et al (2003/0220556 A1).

Torp et al disclose a means for real-time calculation and display of strain in ultrasound imaging and further disclose a sensor adapted to be moved through a blood vessel or body cavity for recording signals from the tissue, wherein the sensor is controlled to acquire signals from the tissue, while being controllably moved in a direction transverse to a measuring plane defined by the sensor; a processor for collecting and processing signals from the sensor to identify strain of the tissue and to relate strain to elasticity or hardness parameters of a tissue surface or tissue volume part; the signals are echographic data detected with an acoustic sensor; a first activating means for activating data storage; and the activating means are connected with the correlation detection means to become active at a predetermined correlation. See Column 5, lines 11-34; Column 6, lines 14-17; Column 7, lines 54-61; Column 8, lines 8-17 and 53-67; and Column 9, lines 1-9.

Torp et al however fail to disclose the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter.

Porat et al disclose a means for tissue characterization and further disclose the sensor is movable through the blood vessel or body cavity for recording signals from tissue while being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor; and the sensor is arranged in a catheter, which

can be inserted into a blood vessel, the sensor recording signals under controlled pull back of the catheter. See Paragraphs 0286 and 0298.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Torp et al to include the ability to move the sensor within a blood vessel, as per the teachings of Porat et al, since it would provide a means of determining a tissue parameter along a length of tissue.

21. Claims 15-17, 19, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) and Porat et al (2003/0220556 A1) as applied to claim 13 above, and further in view of Panescu et al (5,848,969).

Torp et al and Porat et al, as discussed above, disclose a means for measuring a tissue parameter along a length of a blood vessel but fail to disclose a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the heartbeat.

Panescu et al disclose a means for visualizing internal structures and further disclose a position recording means coupled with the processor to record sensor positions; an actuator for controllably moving the sensor in the direction transverse to the measuring plane; the actuator has an adjustable speed of motion; a second activating means for activating the actuator; and the activating means can be connected with an ECG recording device to become active during a predetermined part of the

heartbeat. See Column 3, lines 59-67; Column 4, lines 1-5; Column 6, lines 61-65; Column 10, lines 44-67; Column 11, lines 1-12, 25-35 and 56-63; and Column 17, lines 21-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to control the movement of the sensors, as per the teachings of Panescu et al, since it would provide a means of accurately measuring a tissue parameter along a length of tissue.

22. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471), Porat et al (2003/0220556 A1) and Panescu et al (5,848,969) as applied to claim 1 above, and further in view of Johnson et al (The Probability Density of Spectral Estimates..., 1999).

Torp et al, Porat et al and Panescu et al, as discussed above, disclose a means of determining the tissue hardness, but fail to disclose an optimum overlap is determined by means of a probability function representing similarity between consecutive signals.

Johnson et al disclose the analysis of the statistics of spectral estimates using Welch's technique for spectrum estimation, and further disclose formulae that can be used to determine the optimum overlap of consecutive signals. See whole document.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to determine the optimum overlap of consecutive data, as per the teachings of

Johnson et al, since it would provide a means of ensuring sufficient overlap of the incoming data to accurately determine the tissue type.

23. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al (6,099,471) and Porat et al (2003/0220556 A1) as applied to claim 13 above, and further in view of Johnson et al (The Probability Density of Spectral Estimates..., 1999).

Torp et al and Porat et al, as discussed above, disclose a means of determining the tissue hardness, but fail to disclose an optimum overlap is determined by means of a probability function representing similarity between consecutive signals.

Johnson et al disclose the analysis of the statistics of spectral estimates using Welch's technique for spectrum estimation, and further disclose formulae that can be used to determine the optimum overlap of consecutive signals. See whole document.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Torp et al and Porat et al to include the ability to determine the optimum overlap of consecutive data, as per the teachings of Johnson et al, since it would provide a means of ensuring sufficient overlap of the incoming data to accurately determine the tissue type.

Response to Arguments

24. Applicant's arguments filed July 6, 2010 have been fully considered but they are not persuasive.

Oath/declaration

The Applicant first argues the oath/declaration objection, by stating the changes were performed by the inventor at the time of signing of the oath/declaration. While the changes to the residence, citizenship and address may have been changed at the time of signing, there is no clear indication on the oath/declaration that the changes were indeed made at that time. For the Office to accept the Applicant's statement that the changes were made at the time of signing, would constitute an assumption on the part of the Office that the changes were in fact made at that time. The oath/declaration was signed by all of the inventors on March 15, 2004, but the oath/declaration was not officially submitted to the Office until October 24, 2004. Therefore the changes to the inventor's information could have been made at any time between March 15, 2004 and October 25, 2004. Due to the time period of over 7 months between the signing of the oath/declaration and the final submission to the Office, the Office cannot assume the changes were made at the time of signing, and therefore require the changes to be dated and initialed.

With respect to the 112 6th paragraph matters, the Applicant has stated all of the claimed means constitute "some form of computer/program control element", and therefore constitutes a "programmed processor". The Applicant's response is insufficient to overcome the objections and ultimately the rejections of the claims with respect to the claimed means. The Applicants have not provided any specific location in the current specification to support their assertion of a "programmed processor". The current specification is clearly devoid of any specifics pertaining to what explicitly constitutes the claimed "means". Also, per the 112 2nd paragraph rejections regarding

the 112 6th issues memo of September 2, 2008, the corresponding structure for a computer-implemented function must include the algorithm as well as the general purpose computer or microprocessor. The written description of the specification must at least disclose the algorithm that transforms the general purpose microprocessor to a special purpose computer programmed to perform the disclosed algorithm that performs the claimed function. The Applicant may express the algorithm in any understandable terms including as a mathematical formula, in prose, in a flow chart, or in any other manner that provides sufficient structure. Furthermore, as shown in Figure 1, the claimed "correlation detection means", "activating means" (including the claimed "first" and "second" activating means) are all separate from processor 4, which would lead one of ordinary skill in the art to deduce the claimed means are not a programmed processor, but a software application that processor 4 operates. The current specification also fails to provide any explicit support for the assumption that the claimed means are "some form of computer/program control element".

Rejection of claims under 112 1st

Regarding the rejection of Claim 19, the Applicant states "it is unclear how the subject matter of claim 19 is not enabled simply because the original specification did not explicitly state whether the function performed by the "second activating means" is carried out by software or hardware". The specification must enable one of ordinary skill in the art to make or use the invention. The current specification fails to provide one of ordinary skill in the art to make or use the invention because the claimed means is not specified to be either a software application or a hardware application. Furthermore,

the Applicants' statement pertaining to the claimed means constitute a "programmed processor" lacks sufficient evidence from the specification, and the Applicants have not provided any specific location in the current specification for supporting their statement. The Applicants further argue Claims 18 and 19, with respect to the claimed "first" and "second" activating means, by stating Figure 1 clearly shows the use of a first and second activating means. Figure 1 shows a single activating means 13, with two separate lines extending therefrom to the actuator 12 and the data storage 15. The current specification clearly discloses in paragraph 0025, activating means is provided to activate data storage, and "further activating means may be provided to activate the actuator". Figure 1 shows an activating means performing functions that are not supported by the current specification, and also fails to clearly show the use of two separate distinct activating means to perform the different tasks in Claims 18 and 19.

Regarding Claims 25 and 26, the Applicants argue the Examiner has not provided a list of probability functions that would not work with the current invention, and one of ordinary skill in the art would be able to identify a suitable probability function to carry out the current invention. The Applicants cannot broadly claim the use of every/any probability function. In order to identify any specific probability function that would work with the current invention would require undue experimentation on the part of one of ordinary skill in the art trying to make or use the invention. Again, the current specification must be written such that one of ordinary skill in the art would be able to make or use the current invention.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the comparison is being performed between signal data from consecutive image sets (slices)) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, any data (echographic or optical) is not an image. The data is used to form an image.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the optimal overlap determines whether two consecutive signals are sufficiently similar to perform a stress/strain analysis) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Rejection of claim under 112 2nd

The Applicants traverse the rejection of Claims 14, 18 and 19, and state they have no intention to limit the claimed invention to either a special purpose hardware or a general purpose processor with application specific software. As stated above, the Applicants have not provided any algorithm for performing the claimed functions, nor have the Applicants provided any indication that the functions are performed by special hardware. By stating the Applicants have no intention to limit the claimed functions to either a software application or a hardware application, is the definition of indefinite. The

Applicants must distinctly claim what is performing the function such that one of ordinary skill in the art can determine how the invention works, otherwise the claimed subject matter is indefinite.

Regarding Claims 25 and 26, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., strain is identified by comparing two image planes to determine changes; and the optimum overlap relates to the need to compare two substantially similar consecutive image slices under two different pressures) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

101 rejections

The Applicants argue the Bilski rejection of Claims 1-8 and 10-12 is improper because Claim 1 provides a concrete output. Claim 1, as currently written, provides no specific output. Claim 1 ultimately relates the strain to either hardness or elasticity of tissue, but it does not provide a concrete output. The definition of "concrete", per the MPEP, means "reproducible". The current claim language of Claim 1 only determines from the strain the hardness or elasticity of tissue; there is no output for someone to verify the measurement or ultimate determination of the tissue. Since no one can visually verify the measurement or ultimate determination of the tissue parameters in order to reproduce the results, the claim fails to provide a concrete output.

Regarding Claims 14, 18 and 19, the 101 rejections are being maintained because the Applicants have not provided specific support in the current specification with respect to the assertion the claimed means are a “programmed processor”. As stated above, Figure 1 appears to contradict the Applicants' assertion of a “programmed processor”, since all of the claimed means are associated with a separate processor 4, and therefore the claimed means can be reasonably interpreted as nothing more than software. Since software is an intangible medium and an abstract idea, the claimed means constitutes non-statutory subject matter.

Prior art rejections

Regarding currently amended Claim 1, the current rejection is relying upon the prior art of Panescu et al to teach the use of an actuator.

25. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., consecutive images are rendered by a sensor that is controllably moved in a transverse direction while acquiring image signal sets) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicants argue the combination of Torp et al and Porat et al fail to teach several elements in Claims 1 and 13. In particular, Torp et al fail to teach “relating strain to at least one of either hardness or elasticity parameters of the tissue”, but instead measures the rate of change in strain. As previously discussed, in order to determine

the rate of change in strain, one must first measure the strain. Therefore, by determining the rate of change in strain, Torp et al also disclose the determination of the strain. In Torp et al, the strain measurement is correlated to the hardness of plaque (a type of tissue) in the blood vessel. Therefore Torp et al does teach the claimed limitation.

The Applicants further argue Porat et al fail to disclose the direction of the sensor's motion, or specifically whether the sensor's direction is transverse to the measuring plane. As discussed above, the measuring plane can be interpreted as the sensor's point of contact that is parallel to the tissue surface, and the sensor is moved in a direction transverse to the measuring plane to provide sensor contact with the tissue (Figure 2C). With the device inside a blood vessel to measure the hardness of plaque, the sensor must move transverse to the measuring plane by extending in a direction transverse to the longitudinal axis of the medical device and the blood vessel wall. Otherwise, a sensor contacting plaque at any other angle would increase the risk of dislodging the plaque and further increase the risk of a heart attack, stroke, or even a pulmonary embolism. The Applicants further argue Porat et al fails to disclose the "tissue is subject to varying pressure". The Examiner would like to note the invention of Porat et al is intended to be used with a living person. Therefore, blood vessel pulsation due to a beating heart is inherently encountered.

In response to applicant's argument that Torp et al fail to disclose a "display device for displaying elasticity and/or hardness parameters of a tissue surface", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The display 7 in Torp et al is capable of displaying the calculated strain from the strain calculation 14.

The Applicants again argue the device in Porat et al is not movable through a blood vessel. The Examiner would like to again point out Paragraph 0286, wherein the placement of the inventive device is clearly disclosed to be placed within a blood vessel. The Applicants further argue Porat et al is not arranged in a catheter. See Paragraphs 0240 and 0257 for the disclosure of placing the sensing system within a catheter.

Regarding Claim 12, the Applicants argue Panescu et al fail to disclose the tissue is moving during the measurement, and the sensor is moved parallel to the tissue's direction of motion such that the sensor has a fixed position. The Examiner would like to note the invention of Panescu et al is intended to be used with a living person. Therefore, blood vessel pulsation due to a beating heart is inherently encountered. The Examiner would also like to note the movement of the blood vessel during the heart beat cycle is not longitudinal, such that the length of the blood vessel does not become longer and then shorter during the cycle. The movement of the vessel is radially in a longitudinal direction along the length of the vessel, such that the pulse of blood being moved from the heart is forced out in pulses, ultimately causing the outward expansion and contraction of the vessel wall along the length of the vessel. Since the vessel wall moves outwardly, the sensor also moves in the same direction as the vessel wall.

26. Regarding Claims 25 and 26, In response to applicant's argument that there is no teaching, suggestion, or motivation to combine the references, the examiner recognizes

that obviousness may be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988), *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992), and *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007). In this case, Torp et al teach the calculation of strain can be performed with an arbitrary degree of overlap between the signal packets, and therefore teach the use of an overlap, but not determining the "optimum overlap" to perform the calculation. Johnson et al teach determining the amount of overlap.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736